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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/784,476	02/23/2004	Alan R. Fritzberg	295.044US3	1730

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EXAMINER

JONES, DAMERON LEVEST

ART UNIT	PAPER NUMBER
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1618

DATE MAILED: 06/16/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/784,476

Applicant(s)

Fritzberg

Examiner

D. L. Jones

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 4/28/05; 6/21/04; and 6/7/04.
- 2a) ☐ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 52,53,80,81 and 86-95 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 52,53,80,81 and 86-95 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. <u>4/28/05</u> |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)                                 |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **VACATE PREVIOUS OFFICE ACTION**

1. The previous office action is vacated in light of the interview on 4/28/04 and the three preliminary actions that were submitted on 2/23/04, 6/7/04, and 6/21/04. Thus, the following action is necessary.

### **ACKNOWLEDGMENTS**

2. The Examiner acknowledges receipt of the amendment filed 2/23/04 wherein the specification was amended. Also, the Examiner acknowledges the first preliminary amendment filed 6/7/04 wherein claims 1-51, 54-79, and 82-85 were canceled and claim 81 was amended. In addition, the Examiner acknowledges receipt of the third amendment filed 6/21/04 wherein claims 86-95 were added.

**Note:** Claims 52, 53, 80, 81, and 86-95 are pending.

### **RESTRICTION INTO GROUPS**

3. Restriction to one of the following inventions is required under 35 U.S.C. 121:
- I. Claims 52 and 53, drawn to a method of treating non-cancerous diseases in or near bone as set forth in independent claim 522, classified in class 424, subclass 1.11+.
  - II. Claims 80 and 81, drawn to a method of treating a subject afflicted with a hematopoietic genetic defect as set forth in independent claim 80, classified in class 424, subclass 1.11+.

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III. Claims 86-95, drawn to a method of treating osteomyelitis as set forth in independent claim 86, classified in class 424, subclass 1.11+.

4. The inventions are distinct, each from the other because of the following reasons: Inventions I-III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the inventions are distinct because independent claim 52 is directed to treating a non-cancerous diseases, independent claim 80 is directed to a treating a hematopoietic genetic defect which includes cancerous diseases; and independent claim 86 is directed to treating osteomyelitis (bone infection). It should be noted that for independent claims 52 the non-cancerous disease is in or near bone while independent claim 86 is directed to bone infection. Furthermore, it is noted that in each of the three independent claims 52, 80, and 86, the methods involve administering a radionuclide complexed with a bone targeting agent.

**Note:** It should be noted that while the methods have been classified in the same area, they are distinct from one another because prior art used against one method would neither anticipate nor render obvious that same radionuclide-bone targeting ligand complex for another method. Hence, a separate search of the art for each invention is necessary.

5. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

#### **ELECTION OF SPECIES**

6. Claims 52, 53, 80, 81, and 86-95 are generic to a plurality of disclosed patentably distinct species comprising a radionuclide complexed with a bone targeting ligand. In particular, it is noted that for independent claim 52, various non-cancerous diseases are encompassed by the claim as well as various radionuclide-bone targeting ligand complexes. For independent claim 80, various hematopoietic genetic defects are encompassed by the claim as well as radionuclide-bone targeting ligand complexes. For independent claim 86, a bone infection is being treated with a radionuclide-bone targeting ligand complex. Furthermore various radionuclide-bone targeting ligands may be utilized (i.e., arsenic-77, molybdenum-99, and rhodium-105 in combination with, for example, DOTMP, ethane-1-hydroxy-1,1-disphosphonic acid, or ethylenediaminetetramethylene phosphonic acid). Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

**Note:** Applicant is respectfully requested to elect a radionuclide-bone targeting ligand complex from within the elected group. In addition, if Group I is elected, Applicant is respectfully requested to identify the non-cancerous disease being treated.

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If Group II is elected, Applicant is respectfully requested to identify the hematopoietic genetic defect being treated.

7. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

8. Due to the complexity of the restriction requirement a telephone call requesting an oral election to the above restriction requirement was not made.

9. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement is traversed (37 CFR 1.143).

10. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).


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11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. L. Jones whose telephone number is (571) 272-0617.

The examiner can normally be reached on Mon.-Fri., 6:45 a.m. - 3:15 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
D. L. Jones  
Primary Examiner  
Art Unit 1616

May 2, 2005